

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

[UNDER SEAL])	CIVIL ACTION NO. _____
)	
)	
Plaintiffs,)	
)	
v.)	
)	
[UNDER SEAL])	
)	
Defendant.)	
_____)	

COMPLAINT

CONFIDENTIAL – FILED UNDER SEAL

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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

UNITED STATES OF AMERICA,)	CIVIL ACTION NO. _____
EX REL. THOMAS P. BURRIS,)	
)	
Plaintiffs,)	
)	
v.)	
)	FILED IN CAMERA AND
THE SCRIPPS RESEARCH INSTITUTE)	UNDER SEAL
)	
Defendant.)	JURY TRIAL DEMANDED

**COMPLAINT FOR DAMAGES AND OTHER RELIEF
UNDER THE QUI TAM PROVISIONS OF THE
FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 *et seq.*]**

On behalf of the United States of America, Plaintiff Relator Thomas P. Burris (“Relator”), brings this action to recover treble damages and civil penalties against The Scripps Research Institute (“Scripps” or “Defendant”) for violations of the Federal False Claims Act, 31 U.S.C. §3729 *et seq.*

I. OVERVIEW OF THE CASE

1. This action alleges that Defendant Scripps knowingly overcharged the United States for unallowable costs on federal research grants, specifically compensation to researchers for time and effort spent on activities unrelated to the awarded grants.

2. Scripps is a private, non-profit biomedical research institution with two campuses in the United States, one in La Jolla, California and one in Jupiter, Florida. It is one of the largest non-profit medical research institutions in the United States. Federal research grants are the lifeblood of Scripps’ operations. From 2008 through 2014, Scripps applied for and received from the National Institutes of Health (NIH) over \$1.5 billion dollars in research grant funding. Each year Scripps is awarded grant money in the amount of approximately \$250,000,000. Since

2009, over 85% of such grant money was from federal grants and in the past several years, 90-95% of the research grant money was from the NIH.

3. Scripps is a prestigious medical research institution which has employed Nobel Prize winners and Members of the National Academy of Sciences. It is a highly coveted position for its faculty and is viewed with great respect by the public and the scientific community. Unlike academic institutions and universities which have multiple sources of revenue such as tuition, state funding and large endowment funds, Scripps relies to a greater extent, and very substantially, on federal grant funding. Scripps must continually submit new grant applications and receive grant awards to continue to function. This is especially true because only approximately 7-15% of NIH grant applications (or resubmissions) are successful and even, if awarded, grant funding is limited in time, typically only lasting for 2-4 years.

4. Drafting a new federal grant application takes a significant amount of time and effort. For a new grant application, resubmission or renewal ("grant application"), the principal investigator (PI), faculty and other research staff (*e.g.*, postdoctoral fellows, staff scientists and research associates), with the assistance and supervision of Scripps' Office of Sponsored Programs, may spend hundreds of hours compiling, drafting, revising and finalizing the information included in the grant application. The grant application requires a description of the research project, the key personnel who will work on the research, a detailed budget and a specific research plan which explains all the scientific data in detail. It is not uncommon for a grant application to run to hundreds of pages. The most labor intensive part of the application is obtaining the scientific data which involves considerable research into the scientific literature and the design of experiments that support a research hypothesis.

5. In a grant application, the requested budget includes the compensation for the key personnel who will be working on the grant research. The salaries of the researchers typically make up a significant portion of the costs of the grant. At Scripps, salaries of researchers are usually 60% or more of the grant amount requested which is larger than what is seen at other academic institutions. The portion of a researcher's salary charged to a grant is expressed as a percentage of the researcher's time and effort s/he plans to devote to the grant research out of the researcher's total professional activity for which s/he is employed. Total professional activity, which includes new grant applications and research, teaching, and other administrative activities, equals 100% and is not based on a 40 hour work week. For example, if the researcher's total salary is \$100,000 and he plans to spend 6 months (50% effort) working on a particular grant's research, then the grant application would request \$50,000 in grant funding to cover the cost of his salary.

6. Under the law, a grant recipient institution may only charge a federal grant for the percentage of a researcher's salary commensurate with the time and effort actually expended by the researcher for work on that grant. This ensures that the federal government gets the full benefit of the research commitment it is paying for, as promised in the grant. The recipient institution must follow certain effort reporting procedures and requirements to confirm that each researcher's time and effort spent on awarded grants is accurately allocated among the grants (if working on multiple grants) and reasonably reflects the individual's actual work on each grant.

7. Beginning no later than 2008 and continuing, upon information and belief, through the present ("the relevant time period"), Defendant Scripps has improperly overcharged awarded federal grants for the time and effort of PIs, faculty and research personnel spent drafting new grant applications. New grant application activity is not chargeable to awarded

grants as it is unrelated to the research under the awarded grants and does not benefit the awarded grants.

8. Scripps committed this fraud through its “soft money policy” requiring all faculty to cover 100% of their salaries through grant funding. The only other possible source of funds for faculty is a one time, non-renewable start-up account which faculty was disincentivized to use for salary coverage. In order to achieve and maintain a steady stream of grant funding, PIs, with the assistance of other faculty and research staff, needed to continually write and compile data for new grant applications and resubmissions. Generally, faculty and their researchers needed to be working on and funded by at least 2 or 3 overlapping awarded grants at all times to achieve 100% salary coverage. This was extremely difficult to maintain because awarded grants are short-lived (only lasting approximately 2-4 years) and the chances for NIH approval of new grant applications are low (only about 7-15% of NIH applications are approved). Even if there were overlapping active, awarded grants, 100% salary coverage could not be legitimately achieved because faculty was required to work on and apply for new grant applications and many were also engaged in teaching and administrative activities unrelated to awarded grants. Those activities diminished the work effort reportable on awarded grants to substantially less than 100%. Scripps defrauded the federal government by failing to properly account for new grant application activity and unrelated teaching and administrative activity by its PIs and researchers and consequently overcharged awarded grants by submitting false claims for reimbursement.

9. By way of example, from 2008 through 2013, Relator worked on a total of 8 awarded research grant projects totaling over \$10 million dollars in federal funding, while also preparing and submitting at least 18 new grants/resubmissions that were never awarded. During

this period, Relator estimates that he spent between 20-50% of his working time on grant proposal activity. Further, he estimates that other faculty and research staff spent a significant amount of their time assisting him in preparing the grant applications. Thus, Scripps knowingly overcharged the 8 awarded grants for Relator's salary by 20-50% for his time and a portion of the other researchers' time spent on activity not related to those grants, namely, writing and compiling the data for eighteen other grant applications or resubmissions. In fact, for at least two years, from approximately March 2011 through March 2013, Relator's evidence shows that Scripps charged 100% of Relator's salary to awarded federal grants without regard to his considerable effort spent drafting new grant applications or resubmissions.

10. Based on what he saw Scripps do with his own salary being billed excessively to the federal grants and other indications which will be set forth herein, Relator has observed that Scripps is systematically and unlawfully overcharging the government awarded grants by 20-50% for costs associated with new grant application activity, teaching and other non-related administrative work which are not part of the awarded grants. Relator has knowledge that this improper billing was widespread, spanning grant research conducted at both of Scripps' campuses and encompassing fraudulent allocation of salaries of numerous PIs, faculty and research staff.

11. Scripps conducted this fraud without the knowledge of the researchers. Scripps kept the researchers "in the dark" about how to accurately report their time spent on new grant proposals by failing to provide any policies, procedures, guidance or training on the issue. Due to Scripps' lack of compliance training or guidance, Relator did not understand how to accurately report his time spent writing new grant applications and resubmissions. It is Relator's belief that other faculty, even those who held previous positions at other institutions, did not

comprehend that Scripps was improperly billing for their time and effort spent on grant proposal activity and other unrelated teaching and administrative work. Relator believed that billing 100% of salaries to awarded grants must be allowable, because Scripps is such a prestigious institution, and he and other faculty were expected to do so

12. PIs did not directly submit grant applications or reports to the government. Scripps, as the grant recipient, submitted the grant applications and bore the primary responsibility for compliance. PIs did review internal Scripps reports, such as effort reports and account payroll reports, which were not directly submitted to the government. Scripps required Relator to fill out a two-page effort report each month which was knowingly misleading and ambiguous in that it did not distinguish between time and effort spent on awarded grants as opposed to new grant applications, did not clarify what was research and teaching time, as opposed to administrative time, and did not permit faculty to know what time was being billed to awarded grants as opposed to non-billable time spent on grant applications, teaching or other administrative activities. This is set forth in detail in paragraphs 103 and 104 herein. Importantly, neither of the internal Scripps reports requested the faculty to separate out time and effort spent on awarded grants from that spent on new grant application activity or unrelated teaching and other administrative tasks.

13. In sum, throughout the relevant time period, Scripps has knowingly overcharged numerous awarded grants for costs associated with writing and research connected with new grant applications and resubmissions and unrelated teaching and administrative tasks costs which are not allowable or directly allocable to already-awarded grants. As a result, the United States has suffered millions of dollars in damages by overpaying for the costs associated with researchers' time and effort on federal grants and teaching which were unrelated and not lawfully

chargeable to awarded grants. The United States was defrauded because it lost the value of the promised time which should have been spent on important medical research, but instead was diverted to other unrelated activities which benefited Scripps at the government's expense.

II. PARTIES

14. The United States is a plaintiff to this action. Through its agencies, including the National Institutes of Health, located in Bethesda, MD, and others, it awards and administers federal research grants.

15. Relator Thomas P. Burris, Ph.D. is a United States citizen and resident of Columbia, Illinois. From September 2008 through December 2013 at Scripps Florida, he served as a tenured Professor of the Department of Molecular Therapeutics and also, from 2009 through 2013, as a Professor of the Department of Metabolism and Aging. While working at Scripps, he worked on eight research grants totaling over \$10 million dollars in federal funding. His research focused in part on developing drugs targeting nuclear receptors for treatment of diseases including Type 2 Diabetes, Heart Disease, Cancer and Alzheimer's. The allegations in this Complaint are based upon information Relator discovered through his work at Scripps and through his own personal efforts, observations and investigations. There has been no public disclosure of the fraudulent transactions described in this Complaint, and even if there were, Dr. Burris qualifies as an original source within the meaning of the False Claims Act.

16. Defendant, The Scripps Research Institute, is a private, non-profit research institution which focuses on biomedical research in such fields as cancer biology, infectious diseases, molecular therapeutics and neuroscience. It is one of the largest and most prestigious such institutions in the United States. More than 200 principal investigators work at Scripps. Scripps has two locations in the United States: in La Jolla, California and Jupiter, Florida. From 2008 through 2014, Scripps received over \$1.5 billion dollars in federal research grants.

III. JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732.

18. This Court may exercise personal jurisdiction over Defendant pursuant to 31 U.S.C. §3732(a) and because Defendant transacts business with the National Institute of Health in the District of Maryland.

19. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because Defendant can be found in, reside in, and/or transact business in the District of Maryland. In addition, the submission of false claims Act false records, as alleged herein, occurred, and continue to occur, in this District.

IV. THE LAW

A. The Federal False Claims Act

20. The Federal False Claims Act (“FCA”) provides, among other things, that any person who (1) “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;” (2) “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;” or (3) “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,” is liable to the United States for a civil monetary penalty plus treble damages. 31 U.S.C. §§ 3729(a)(1)(A), (B) and (G).

21. The term “knowingly” means “that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. §§ 3729(b)(1)(A)(i)-(iii). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

22. The term “claim” means “any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded” 31 U.S.C. §§ 3729(b)(2)(A)(i)-(ii).

23. “[T]he term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

B. Federal Law Governing Grants

24. The federal government awards billions of dollars in grant funding to thousands of entities each year. For 2015 alone, NIH projects that it will award over \$30 billion in research grants to recipient organizations.

25. To ensure the proper use of grant funding, the government has established regulations setting forth uniform administrative requirements, cost principles and audit requirements for federal awards to grant recipients such as to non-profit organizations like Scripps, institutions of higher education, hospitals and numerous other entities receiving federal grants. *See* 2 C.F.R. Subt. A, Ch. II, Pt. 200. These regulations standardize the requirements for the federal agencies awarding and administering grants, as well as the entities receiving the grant funding.

26. Critical to this Complaint are the federal cost principles. These cost principles govern the “allowable costs of work performed by the [recipient entity] under Federal awards.” 2 C.F.R. § 200.401(a). Generally, in order to be allowable under Federal awards, costs must “[b]e

necessary and reasonable for the performance of the Federal award and be *allocable* thereto under these principles” and “adequately documented.” 2 C.F.R. § 200.403(g) (emphasis added).

27. Scripps, as the grant recipient bears “the primary responsibility for employing whatever form of sound organization and management techniques [which] may be necessary in order to assure proper and efficient administration of the Federal award.” 2 C.F.R. § 200.400(c). Thus, Scripps bears the burden of ensuring that only allowable costs are charged to federal grants.

28. The specific federal cost principles that apply to a particular grant depend on the type of recipient entity. 2 C.F.R. § 215.27. For non-profits, the relevant cost principles are found at 2 C.F.R. Part 230, Cost Principles for Non-Profit Organizations (The Office of Management and Budget Circular A-122). These cost principles are used “by all Federal agencies in determining the costs of work performed by non-profit organizations under grants.” *Id.* § 230.20.

29. There is a specific section of the cost principles discussing compensation paid to PIs and other researchers for conducting grant research. Salaries (and fringe benefits, such as healthcare, life insurance and retirement benefits) often make up a significant portion of the costs of grants. The portion of a researcher’s salary (and fringe benefits) charged to a grant is calculated based on the percentage of the researcher’s total time and effort s/he devotes to the grant research. Total effort or professional activity of the researcher must equal 100%, include all professional activities and is not based on a 40 hour work week.

30. Thus, the cost principles establish certain effort reporting procedures and requirements to ensure that the government is paying for and receiving the amount of time and effort promised by the grant recipient. In general, compensation for a researcher’s time and

effort is allowable to the extent it reasonably reflects the actual activity of the researcher **for work on the grant.**

31. The regulations require that the organization maintain “documented payrolls approved by a responsible official(s) of the organization” in order to charge federal grant awards for the salaries and other compensation for personnel. *Id.*, Attach. B, § 8.m. Thus, charges to awards for employees’ salaries must be supported by “documented payrolls.”

32. In addition, the organization must keep “personnel activity reports,” also known as “effort reports” reflecting the distribution of work of each employee. 2 C.F.R. Part 230 Appendix B para. 8(m)(2). In order to charge an award for the employee’s time and effort, the effort reports must meet the following specific requirements:

(a) The reports must reflect an after-the-fact determination of the actual activity of each employee. Budget estimates (i.e., estimates determined before the services are performed) do not qualify as support for charges to awards.

(b) Each report must account for the *total activity for which employees are compensated and which is required in fulfillment of their obligations to the organization*.

(c) The report must be signed by the individual employee, or by a responsible supervisory official having first hand knowledge of the activities performed by the employee, that the distribution of activity represents a reasonable estimate of the actual work performed by the employee during the periods covered by the reports.

(d) The reports must be prepared at least monthly and must coincide with one or more pay periods.

Id. (emphases added); 2 C.F.R. Appendix B to Part 230 para. 8(m)(2); *see also* U.S. Department of Health and Human Services, NIH, *NIH Grants Policy Statement*, Oct. 1, 2013 (stating that salaries of research personnel are only allowable to the extent that they “**reasonably reflect the percentage of time actually devoted to the NIH-funded project.**”) (emphasis added).

33. The HHS Office of Inspector General (“OIG”) has identified effort reporting as a particular risk area for fraud in connection with federal research grants. They view it as a critical risk area because “many researchers have multiple responsibilities . . . that must be accurately measured and monitored” and that throughout the researcher’s workday, it may be hard to keep track of the time and effort spent on activities. Thus, the OIG stresses that **“institutions need to be especially vigilant in accurately reporting the percentage of time devoted to projects.”** HHS-OIG, “Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards” 70 Fed. Reg. 71312 (Nov. 28, 2005).

V. THE FALSE CLAIMS ACT SCHEME

34. Contrary to federal cost principles discussed above, Scripps knowingly overbilled federal grants for researchers’ time and effort not chargeable to federal grants.

- Section A below discusses how Scripps made false representations and certifications regarding the researchers’ committed level of effort in grant applications and in subsequent reports submitted to NIH to obtain grant funding. . These applications and reports were false and fraudulent in that they overstated the level of research effort promised by researchers by including in the grant application the researchers’ time which they knew would be spent working on new grant proposals which could not be charged to awarded grants.
- Section B describes Scripps’ “soft money policy” requiring researchers to cover 100% of their salaries to federal grants without properly accounting for new grant application activity and unrelated teaching and administrative work which could not be charged to awarded grants.

- Section C sets forth how Scripps overbilled awarded grants by 20-50% by charging time spent on unallowable grant application activity, teaching time and administrative time. This section provides a detailed analysis of Relator's work efforts during 2012 when he worked on 4 awarded Federal grants and 6 new grant applications. 100% of his salary was charged to the awarded grants when 44% of his time was expended on new grant applications.
- Section D sets forth how Scripps failed to provide training or guidance to its researchers as to how to properly account for their time and effort spent in preparing new grant applications and resubmissions and actually misled researchers by providing an internal form which did not distinguish between time and effort spent on awarded grants as opposed to new grant applications, teaching or other activities not chargeable to the grant. In addition, Scripps policies, procedures and internal controls for tracking and accurately charging awarded grants for researchers' time and effort were recklessly or intentionally inadequate and led to Scripps submitting false reports, certifications and claims.

A. Scripps Made False Representations and Certifications in Grant Applications Regarding Time and Effort to be Expended

1. The Grant Applications Were False

35. Beginning with a new grant application, entities requesting federal funding are required to make specific certifications and assurances to the government. The application for NIH funding is called the SF 424 Research and Related (R&R) Form and includes, *inter alia*, information about the applicant entity (project site, resources, equipment, etc.), a description of the research plan with detailed scientific data, a requested budget and a list of personnel who will work on the research, as well as the time they will devote to the research.

36. In the budget section of the grant application, the applicant lists the total requested funding amount, the key personnel who will work on the research project, the amount of time they will devote to the project and their requested total compensation for that work. Compensation or salaries of the key personnel often account for a significant portion of the requested grant funding. The PI typically looks at the science involved in the research and selects the appropriate research staff and time commitment. In addition to the PI, individuals working on grant research can include co-investigators, postdoctoral fellows, staff scientists and research associates. The time and effort the personnel will devote to the project is expressed as “person months.” Thus, the applicant must identify the number of months devoted to the project for each designated person.

37. For example, a grant may designate the PI as working 4 calendar months (34% of his time and effort) each year on a three-year grant. If the institution represented this in a grant application when it knew or recklessly ignored the fact that the PI will only work 1.5 months (12.5% of his time and effort) each year because the PI is required to write and compile new grant applications, a fraud was committed. This is what Scripps did.

38. The authorized representative of the applicant must sign the application and certify the following:

By signing the application, I certify (1) to the statements contained in the list of certifications . . . and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances . . . and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

39. In addition to the certification on the face of the NIH SF 424 R&R application, there is an application guide which includes the following directions to the applicant organization:

The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. *The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.*

DHHS, PHS, “SF 424 (R&R) Application Guide for NIH and Other PHS Agencies” (updated Nov. 25, 2014), page 69 (emphases added).

40. At Scripps, Kaye I. Wynne, Vice President of the Office of Sponsored Programs (and part of Scripps’ Executive Management Team) was often listed on applications as the authorized representative. The SF 424 R&R Form also required a signature of the authorized representative. Sometimes the individual signing would be different than the authorized representative. For the signature of the authorized representative, Relator has seen the names of the following individuals signing (electronically) the application before submission to the government: Kaye I. Wynne (Vice President, Office of Sponsored Programs) in addition to Pamela Graham, (Grants Administration, Pre-Award Administration) Lawrence Douglass (Grants Manager, Office of Sponsored Programs), Fred Heaton (Manager of Pre-Award Administration) and Kalina Aki (Grants Administrator, Pre-Award Administration).

41. Scripps' Office of Sponsored Programs (OSP) handles all aspects of grant and contract funding including pre-award applications, grants management and administration. The office is located in La Jolla, and there is a satellite office at the Scripps Florida campus. Fred Heaton, based at Scripps La Jolla, served as the OSP's manager of pre-award administration, assisting PIs at both campuses with grant proposal applications. In approximately 2010, Scripps transferred OSP La Jolla employee Lawrence Douglass to Scripps Florida to assist with the grant proposal applications of the Florida researchers. Once a grant was awarded, Kathy Strickland handled grant administration for the Florida researchers and another individual in La Jolla assisted the La Jolla researchers.

2. The Just in Time Reports Were False

42. Before the government approves a grant application, the government may request a "Just in Time Report" from the applicant. This report requests additional information including "other support" information concerning both active and pending grant awards for the key personnel in the pending application. This report will show if the PI, faculty and other research staff have time to perform the work on the new, proposed grant in light of their commitments to work on already-awarded grants. When NIH asks for other support information, it is "requested for all individuals designated in an application as senior/key personnel – those devoting measurable effort to a project." *NIH Grants Policy Statement*, Part I, para 2.5.1. The government will review this information to ensure that "[s]ufficient levels of effort are committed to the project." *Id.* The applicant's responsibility to verify the accuracy of information submitted extends to the Just in Time Reports. *Id.*

3. Scripps' False Certifications and False Claims For Payment Due To Misrepresentations Regarding Level of Effort to be Committed And Being Committed By PIs and Other Researchers

43. If the grant is awarded, the recipient organization is bound by the terms and conditions set forth in the Notice of Award (NOA). The terms and conditions of the NOA state that the award is based on the grant application and is subject to, *inter alia*, those terms and conditions set forth in the *NIH Grants Policy Statement* and federal regulations governing grants. *The NIH Grants Policy Statement* and the relevant federal regulations regarding costs charged to grants and time and effort reporting are discussed in Section IV.B. above. In brief, the requirements relevant to this Complaint are that grant recipient institutions must only charge awarded grants for researchers' time and effort actually spent working on the specific grants and must accurately track and document the researchers' time and effort and must allocate only time spent on grant work to the grant.

44. The NOA includes the total amount award, as well as the award calculation including salaries, wages and fringe benefits based on the time and effort of the key personnel committed to work on the research. An important factor in awarding grants is the level of effort to be committed by the PI, as well as the other designated personnel to be conducting the research.

45. The government may terminate the award if the recipient organization materially fails to comply with the terms and conditions of the award. 2 C.F.R. 215.61

46. The NOA states that the recipient organization accepts the award "when funds are drawn down or otherwise obtained from the grant payment system." Most grants are approved by NIH for grant support for their entire project period (*e.g.*, 3 year project, 5 year project), but only funded in annual budget period increments. Thus, the NOA provides funding for the first budget period, usually lasting a year. *NIH Grants Policy Statement*, Part II Subpt. A-47, ¶ 5.3 Funding. To receive funding of the subsequent budget periods, the recipient organization must

submit annual progress reports. A decision to fund the next budget period is announced in a subsequent Notice of Award reflecting the dates of the next budget period. *Id.*

47. The recipient organization is required to submit progress reports for each grant, usually on an annual basis. These progress reports list the PI, the recipient organization (Scripps), the administrative official (*e.g.*, Kaye I. Wynne) and the signing official (*e.g.*, Lawrence Douglass) and include information, *inter alia*, about the goals of the research, progress in reaching those goals, and the researchers who have worked on the project and their level of effort stated in calendar months.

48. It also includes the following questions about changes to the level of time and effort committed by the key personnel:

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?

If the recipient organization answers in the negative, it is certifying to the government that the key personnel will continue to provide the committed level of time and effort.

49. Lastly, grant recipients “have an obligation to submit a complete and accurate progress report.” *NIH Grants Policy Statement*, Part II Subpt. A-108, ¶ 8.4.1.1.

50. Based on the information in the progress reports, including the key personnel’s time and effort commitment, NIH will decide whether to fund the grant for the next budget period. This decision is announced in a subsequent Notice of Award.

51. When submitting new grant applications and subsequent reports, Scripps misrepresented the level of effort to be devoted to the research and the requested salary by the PI and other key research personnel because it was known that PIs were required to write new grant

applications during the course of every year. Dr. Burris was asked to teach in the Ph.D. graduate program, but offered no compensation (as a percent of salary coverage) to do so. He refused to “volunteer” to teach since it did not help him to cover his requirement that 100% of salary be covered by the federal grants. Relator believes it was the standard for a faculty member to continue to pay their salary at 100% if possible from grants while also “volunteering” to teach. Thus, where a faculty member agreed to teach, the grants were paying for teaching of the students which was an activity not related to the awarded grant. Relator believes that the chair administrative roles may have been done similarly, based on having heard that they did not necessarily receive any percent compensation to cover the administrative duties that they performed. Thus, grant dollars could be paying for them to be administrators as well. The level of effort committed and expended by the key personnel conducting the research was material to the government’s decision to fund a research grant. Further, Scripps expressly and impliedly certified compliance with federal law, including the regulations establishing federal cost accounting principles. Scripps repeatedly and knowingly made false representations in connection with its approved grants and its grant applications because it failed to reasonably accurately reflect the level of effort by the key personnel, failing to take into account the considerable time and effort expended on new grant application activity and unrelated PhD graduate teaching and administrative responsibilities, all of which are not chargeable to awarded grants.

52. As a result, Defendant submitted false claims or caused false claims to be submitted in violation of Sections 3729(a)(1)(A) and (B) of the Federal False Claims Act when it submitted grant applications and subsequent reports containing personnel effort commitments contrary to federal law and regulations. Further, Defendant’s failure to properly reconcile the

effort commitment with the actual effort expended, served to conceal or avoid an obligation to pay or refund money to the government, giving rise to a reverse false claim under Section 3729(a)(1)(G) of the Federal FCA.

B. Scripps’ “Soft Money Policy”: The Expectation That Researchers Cover 100% of Their Salaries Through Federal Grants

53. Scripps expected its faculty, which included its principal investigators, to entirely cover the cost of their own salaries and related benefits through federal grants. The faculty was also responsible for generating the salary for the research staff through the awarded grants. This “soft money policy” was universal throughout Scripps, including at both campuses. It is virtually impossible for a faculty member to legitimately charge 100% of his or her working hours to awarded grants, because all active medical and scientific faculty are required to apply for new research grants every year and many of the faculty have teaching and other administrative responsibilities in connection with the Scripps Ph.D. program. Work efforts on grant applications, teaching, and administrative responsibilities unrelated to the awarded grants are not lawfully chargeable to the awarded grants. Thus if a faculty member engages in any of those very time consuming activities, which almost all do, it is impossible to charge 100% of salary which is translated to 100% work effort to the awarded grants. Most academic and research institutions recognize this and do not require or expect 100% of salaries to be covered by grant money. Scripps is unusual in this respect in requiring this.

54. The 100% soft money policy was impossible to follow because PIs were also required to draft and submit new grant applications during the course of every year. These two requirements were inconsistent and impossible to meet. Typically, an awarded grant only spans 2-4 years and only covers a portion of a researcher’s salary, so, to fully fund their salaries, PIs

and their research staff were always working on generating data and information for new grant applications, in addition to performing research for already-awarded grants.

55. By charging 100% of many PIs and other researchers' time to funded grants, Scripps failed to account for the substantial amount of time and effort spent drafting new grant applications. At the same time, Scripps failed to train or instruct its researchers how to properly account for this time researching and writing new grant applications. Competitive grant application activity is not chargeable to awarded grants as it is unrelated to the research under the approved grants and does not benefit the awarded grants. As explained more fully in Section V.D. below, Scripps kept the researchers "in the dark" about how to accurately account for their time spent on new grant proposals by failing to provide any training or guidance to researchers specifically on the issue. This benefitted Scripps because its operations are highly dependent on grant funding. Because only about 7-15% of the grant applications to NIH since 2008 are approved, and approximately 85-93% are rejected, the substantial time spent by PIs and other researchers would otherwise be lost. By charging such time to awarded grants, Scripps cheats the government and bolster its own operation by recovering revenue from the government that it was not entitled to.

56. By way of background, Scripps is considered a "soft money institution," meaning that it operates based principally on funding through grants from the federal government and other entities. Grant awards from NIH represent the vast majority of Scripps' grant funding. As Scripps is not an institution of higher education, it does not have additional substantial sources of funds such as tuition or substantial endowments, and thus it must rely principally on grants. While it does have Ph.D. and Post Ph.D. programs, the students in these programs do not pay tuition and their work is funded through research grants.

57. Before establishing the Jupiter, Florida location in 2004, the La Jolla location was apparently experiencing financial difficulties. Scripps saw an opportunity to help alleviate the high expenses in La Jolla and expand the institution by opening another campus in Jupiter, Florida. Initially funded by a \$310 million appropriation of federal economic development funds, funds from the State of Florida, as well as local government, Scripps opened its facility in Jupiter in 2008. Since then, it has been able to cover its budget and grow through federal research grants.

58. With no other significant sources of funding, government grants represent the vast bulk of revenues at Scripps. Thus, Scripps has limited ability to pay employees for activities not chargeable to federal grants, *e.g.*, time spent writing and developing new grant proposals. In other words, if Scripps had access to tuition or a large endowment which generated material investment proceeds, Scripps could use that money to pay employees' salaries for work not directly allocable to federal grants. This lack of non-grant funding motivated Scripps to commit the fraud alleged herein.

59. The requirement that researchers cover 100% of their salary through grant funding was conveyed to new hires through the interview process and offer letter. Researchers understood that if they were unable to cover their salaries through grant funding, they were in danger of losing their jobs.

60. When Relator interviewed for the tenured professor position at Scripps in 2008, Scripps made it clear that he would have to cover his salary through his grant funding. Relator received his employment offer from Scripps Executive Vice President and COO, Douglas Bingham, which was conveyed to him by the Chairman of the Department of Molecular Therapeutics, Patrick Griffin, and the Chairman of the Department of Cancer Biology, John

Cleveland, among others. Dr. Griffin is now on the Board of Trustees of Scripps in addition to his employee role. During the interview with Doctors Griffin and Cleveland, it was explicitly stated that Scripps expected grant funding to cover the full cost of Relator's salary.

61. Scripps' offer letter to Relator dated June 10, 2008 discusses the need for grant funding providing his full salary coverage. It is Relator's belief that the offer letter he received was standard for tenure or tenure-track faculty recruits. In the offer letter, Scripps also made available to Relator an Institutional Support Award ("ISA"), which is a onetime, non-renewable account commonly called "start-up funds". He received \$4.5 million dollars to "facilitate the transition of [his] research program to Scripps Florida." Relator believes other faculty received a onetime, non-renewable start-up fund from Scripps as well. Start-up funds typically covered transition costs including hiring new staff, and buying new equipment and supplies to establish a laboratory at a new setting. Relator's ISA funds were to be made available in three equal annual installments. This was a one-time grant and could be used by faculty as a "savings fund." The offer letter includes a series of incentives for *not* spending ISA funds unless absolutely required. For example, if a PI needed to use ISA account funds to cover his salary, the account would be charged his salary plus indirect costs, an amount almost equal to his salary. Thus, the disincentive for not spending ISA funds on salary is that the account would be charged almost double the amount of his salary to cover the indirect costs as well. The letter implies that full salary coverage from grants is expected and ISA funds were only to be used if grant funds are insufficient. Generally, researchers used the start-up funds to set up their laboratories and then closely guarded the remaining funds for salary protection in case their federal grant funding dried up.

62. In the past few years, Relator was involved in helping Scripps identify and recruit potential faculty members. It is Relator's belief that Scripps discussed its "soft money" policy with all recruits. Scripps lost many top-level recruits because it made its soft money policy clear during the interview process and the recruits understood how difficult it is to achieve and maintain 100% coverage of their salaries through federal grant funding. Usually researchers need to have at least 2-3 awarded grants, which overlapped, as well as continually drafting and compiling data for new grant applications, to ensure future funding when the current awarded grants conclude. Faculty felt extreme pressure to make new grant applications and to get new approved grants to avoid a funding gap and to fulfill the 100% salary coverage expected.

63. In an email dated January 15, 2010, a potential Scripps recruit, Wen Xie, indicated his difficulty with Scripps 100% soft money policy:

I cannot commit my candidacy right now. The soft money mechanism is a major concern. In my place, we are doing fine if we could generate 50% of our salary from grants.

Wen Xie chose to stay at the University of Pittsburgh where he remains rather than accept Scripps' offer.

64. In an email dated June 13, 2012, a recruit from the University of Virginia, Ira Schulman, turned down Scripps offer based on what was best for his current research program. Scripps' offer included approximately \$3.2 million dollars in ISA funds. In an email rejecting Scripps' offer, he references the "**100% soft money**" issue at Scripps. Dr. Schulman is still working at the University of Virginia.

65. In another email dated January 7, 2011, a Scripps junior faculty member, Douglas Kojetin, recounted a conversation with a potential faculty candidate for Cancer Biology about how "**Scripps is 100% soft money, and almost all other places are not.**" He noted that the candidate currently only had to cover 30-40% of his salary through grant funding.

66. Scripps was well aware of the difficulties in obtaining full salary coverage through grant funding and the demands of continually preparing new grant applications. Yet Scripps failed to set forth explicit policies and procedures to properly account for the time and effort researchers spent preparing new grants and instead improperly charged awarded grants for these costs.

67. In a Memorandum from the Chairman of the Department of Molecular Therapeutics, Patrick Griffin, to the President of Scripps, Michael Marletta, in November 2011 regarding a Strategic Plan for Molecular Therapeutics, Chairman Griffin indicated that a critical difficulty in recruiting faculty for the Department was due to Scripps' **"pure soft money" policy**. The Memo notes that it is "[e]xtremely challenging to recruit senior faculty to a pure soft money position."

68. Scripps faculty officially reported to the Chairs of their respective Departments and expectations were funneled through the Chairpersons. Since starting at Scripps in 2008 and over the ensuing years, Relator generally remembers many conversations with Patrick Griffin, the Chairman of his department, the Department of Molecular Therapeutics, regarding Scripps' full salary coverage expectation.

69. Further, Relator had numerous conversations over the years with other PIs about the pressure to cover their full salaries through current grant funding. There was enormous pressure to obtain all of their salaries through grants. Relator, and to the best of Relator's knowledge, the other PIs, had no idea it was wrong to bill time spent drafting new grant applications to awarded grants. During his more than 5 years at Scripps, Relator had conversations with the following individuals about the extreme difficulty in maintaining full salary coverage through federal grant funding:

- **Andrew Butler**, former Associate Professor, Department of Metabolism and Aging, Scripps Florida; current Professor, Department of Pharmacological & Physiological Science Saint Louis University School of Medicine;
- **Phil Lo Grasso**, Professor, Department of Molecular Therapeutics, Scripps Florida;
- **Timothy Tellinghuisen**, Associate Professor, Department of Infectious Diseases, Scripps Florida;
- **John Cleveland**, former Professor and Chair, Department of Cancer Biology, Scripps Florida; current Professor and Associate Director of Basic Sciences, Moffitt Cancer Center, University of South Florida;
- **Kendall Nettles**, Associate Professor, Department of Cancer Biology, Scripps Florida;
- **Doug Kojetin**, Associate Professor, Department of Molecular Therapeutics, Scripps Florida;
- **Enrique Saez**, Associate Professor, Department of Chemical Physiology, Scripps La Jolla;
- **Anastasia Kralli**, Associate Professor, Department of Chemical Physiology, Scripps La Jolla;
- **Glenn Micalizio**, former Professor, Department of Chemistry; Scripps Florida; current Professor, Department of Chemistry, Dartmouth.

70. In around October 2011, Relator had a conversation with the then Scripps COO, Doug Bingham, when Mr. Bingham was visiting the Florida campus. Mr. Bingham explained that the principal investigator scientists were really stressed having to cover 100% of their salaries from federal grants. He told Relator that Scripps was considering making a deal with Tenet and opening a hospital in Florida so that Scripps could generate income from the hospital and be able to use it to partly fund researchers' salaries. In an e-mail dated October 14, 2011, Relator followed up with Mr. Bingham asking specifics as to the "realistic expectation of % salary that would be covered and when would this likely be instituted if the hospital plans [were] executed." He also inquired about salary coverage through funded endowed chairs. The Tenet hospital deal was never done, but this conversation and correspondence between COO Bingham and Relator is further evidence which shows that Scripps was aware of the difficulty and pressure involved in having enough federal grant funding for faculty and researchers to cover

their salaries through awarded grants. In addition, in a subsequent conversation, Mr. Bingham discussed with Relator the paucity of donors to fund the endowments for chairs as well as the fact that there were no endowed chairs at the Florida location. This demonstrates the absence of funding sources to cover faculty and researchers salaries and Scripps motivation to file false claims for grant funding. Mr. Bingham is no longer at Scripps.

71. Throughout the relevant time period, there were numerous researchers at Scripps who fully funded their salaries through grant awards and spent a significant amount of time drafting new grant applications in order to maintain full coverage of their salaries. It is Relator's belief that Scripps improperly charged awarded grants for the researchers' time and effort spent on competitive grant proposal activity. In addition, even for researchers who only covered part, and not 100% of their salaries through grant funding, it is likely that those grants were still overcharged. For example, a PI with three grants providing 75% of his salary, still may spend more than 25% of his time putting together new grant applications and resubmissions and, thus, causing Scripps to overcharge the three grants for effort not reasonably related to those grants.

C. Scripps Overbilled Grants by 20-50% For Time and Effort Spent on Unallowable Grant Application Activity

72. Relator estimates that Scripps overcharged federally awarded grants by 20-50% for time and effort spent by researchers on grant application activity. Drafting a new federal grant proposal application or resubmission involves large amounts of time and effort by faculty and researchers. For a new application, the PI and research staff, with the assistance and supervision of the Office of Sponsored Programs, usually spend many hours compiling, drafting, revising and finalizing the information included in the application, the SF 424 R&R Form. The PI and other researchers, including other faculty, postdoctoral fellows, staff scientists and research associates, generally spend up to about 20% of their time on each new grant application

and anywhere from 20-50% of their time if working on multiple new grant applications. Completing the research and writing a new grant application takes anywhere from 1 to 6 months, depending on the nature and scope of the project. The application requires a description of the research project, the key personnel who will work on the research, a detailed budget and a specific research plan which explains all the scientific data in detail.

73. The most labor intensive part of the application is obtaining the experimental evidence included in the grant application. This typically involves considerable research into the scientific literature at the initial stage followed by design of experiments that support a hypothesis that will be tested in the proposed research within the application. This can require hundreds of hours of effort by the PI, as well as from others on the research team. A successful grant application needs to show a reasonable likelihood of success which is done by setting forth supportive experimental evidence in support. The grant application is then reviewed by a panel of scientific experts who rank applications based on a variety of criteria.

74. The vast majority of *initial* grant applications do not get approved. If an application fails to receive funding, the scientific reviewers will give the applicant feedback or critiques as to why it was not awarded. The applicant must address these critiques in order to resubmit the application. This often requires designing and performing additional experiments to address the comments of the reviewers and may require considerable work (e.g. compiling results, analysis of data, redrafting proposal language, etc.) in addition to formatting the resubmission. Scripps charges all of this unfunded experimental work off to existing grants.

75. Relator estimates that writing a grant application typically takes anywhere from a week to a few months. However, one NIH grants officer previously stated that “3-6 months of effort is not unusual for writing a lengthy grant application.” HHS-OIG A-01-04-01506,

“Review of Costs Claimed by Dartmouth College for NIH Grant No. 5 P01 GM51630-06, May 1, 1998-December 31, 2002” (Sept. 2005).

76. Competition for funding is intense, especially from NIH, where 7-15% or less of investigator-initiated applications are funded. Since 2008, it has become harder to receive grant approvals and thus obtain 100% salary coverage via federal grants. With the economic recession beginning in 2008 and the consequent shrinking of NIH’s budget, NIH was able to fund less research. Thus, the grant success rate declined from approximately 30% to only 7-15% and more time had to be spent drafting new proposals and resubmissions. Because of this, PIs and other researchers have to spend considerable amounts of time drafting and resubmitting grant proposals.

77. The large amount of time it takes to write new grant applications demonstrates the falsity of Scripps’ time reporting in connection with awarded grants. The case law holds that such falsity in government grant applications gives rise to damages equal to the full amount of the government grant trebled. In cases such as this where there is no tangible benefit to the government, but rather an intangible benefit to the public through advances in medical research, then the appropriate measure of damages is the amount the government paid in full to Defendant. *See U.S. ex rel. Longhi v. Lithium Power Techs., Inc.* 575 F.3d 458, 472-73 (5th Cir. 2009) (“where there is no tangible benefit to the government and the intangible benefit is impossible to calculate, it is appropriate to value damages in the amount the government actually paid to the Defendants.”); *see also United States ex rel. Feldman v. van Gorp*, 697 F.3d 78, 88 (2d Cir. 2012); *United States ex rel. Laymon v. Bombardier Transp. United States*, 656 F. Supp. 2d 540, 546 (W.D. Pa. 2009).

1. Relator’s Work on Awarded Grants in 2012

78. By way of example, from 2008 through 2013, Relator's salary was funded by awarded research grant projects totaling over \$10 million dollars in federal funding. During this time he, also prepared and submitted at least eighteen new grants/resubmissions that were never awarded. During this period, Relator estimates that he spent between 20 and 50 percent effort on grant proposal activity. Further, for two years, from approximately March 2011 through March 2013, Scripps charged 100% of Relator's salary to awarded federal grants. Throughout the relevant time period, Scripps overcharged the eight awarded grants for Relator's salary by 20-50% for his time spent on activity not related to those grants, namely, writing and compiling the data for eighteen grant applications/resubmissions.

79. For 2012 alone, 100% of Relator's salary was charged to four federally awarded grants in different percentages. During 2012, however, he worked on six new grant applications and resubmissions, completing and submitting three of them during 2012, yet all of his time (salary) was improperly charged to already awarded and funded grants.

80. Specifically, for 2012 alone, Scripps improperly overbilled the awarded grants listed below in Subsections a. through e. The grant applications, Notices of Awards and other submissions commit the key research personnel to devote a specific level of effort to the grant research. Grant funding is dependent on the information included in the application and the terms and conditions set forth in the Notice of Award ("NOA"), including compliance with federal regulations regarding effort reporting. Scripps failed to properly account for researchers' grant proposal activity and, thus, overcharged the following specific grants as detailed below.

a. NIH Grant R01 DK080201 "Regulation of REV-ERBalpha and REV-ERBbeta function by Heme"

81. NIH awarded this \$1.7 million dollar grant to Scripps covering the project period of five years. This grant provides funding to research the biological role of heme as a

physiological ligand for the two orphan receptors REV-ERB α and REV-ERB β . These two receptors play an important role in regulation of physiological processes and may be important targets for design of drugs for treatment of a variety of human diseases. The Applicant Organization is listed as Scripps, the PI is Relator and the Administrative Official and Official Signing is Kaye I. Wynne, Vice President, Office of Sponsored Programs. A significant portion of this grant funding is for salaries and other support for the key personnel who work on the research. The following time and effort were committed to this grant: Relator as PI, 5 calendar months (42% effort); a Postdoctoral Researcher, Yongjun Wang, 4 calendar months (34% effort); a Postdoctoral Researcher, yet to be named, 12 calendar months (100% effort); and a Research Associate, Jin Liu, 9 calendar months (75% effort).

82. NIH issued NOAs for each year of the five years of the grant project which funded the award. For example, the Notice of Award dated April 2, 2012 provided \$388,120 in federal funding for the last year of the project period from April 2012 through the end of March 2013. All of the NOAs state that the recipient organization accepts the award and agrees to abide by the terms and conditions of the award when the recipient draws down funds from the grant payment system. Further, the award of federal grant money is based on the information included in the new grant application and is subject to the terms and conditions set forth in the NOA, including compliance with federal regulations regarding effort reporting requirements.

b. NIH Grant R01MH092769 “Development of ROR Ligands for Treatment of Circadian Rhythm Disorders”

83. NIH awarded Scripps this \$4.6 million dollar grant for a four year period. This grant provides funding to design and develop synthetic compounds that regulate the ROR receptors that are regulators of the mammalian circadian rhythm. This research involved possible treatments for sleep disorders as well as other disorders associated with dysregulation of

the circadian rhythm including bipolar disorder and schizophrenia. Dysregulation of the circadian rhythm is associated with a range of human diseases and the research is focused on determining if regulation of RORs by drug like molecules would hold utility in treatment of human disease. The grant application listed Kaye I. Wynne, Vice President of the Office of Sponsored Programs at Scripps as the Authorized Representative and Pamela Graham signed the application. The following time and effort were committed to this grant: Relator as PI, 5 calendar months (42% effort); a co-investigator Patrick Griffin, .60 calendar months (5%); a co-investigator Andrew Butler, 1.20 calendar months (10%), a co-investigator Theodore Kamenecka, 1.20 calendar months (10%) and 5 Post Doctoral Associates, 7 calendar months each (58% effort) for a total of 35 months.

84. NIH issued Notices of Award (“NOAs”) for each year of the four years of the grant project which funded the award. For example, the Notice of Award dated November 3, 2011 provided \$680,084 in federal funding for the budget period from December 2011 through the end of November 2012. The NOA dated April 19, 2012 increased the funding for that budget period by an additional \$64,299. The NOA dated November 23, 2012 provided \$669,947 in federal funding for the budget period from December 2012 through the end of November 2013. All of the NOAs state that the recipient organization accepts the award and agrees to abide by the terms and conditions of the award when the recipient draws down funds from the grant payment system. Further, the award of federal grant money is based on the information included in the new grant application and is subject to the terms and conditions set for in the NOA, including compliance with federal regulations regarding effort reporting requirements.

85. Scripps submitted a Progress Report to NIH for this grant on November 5, 2013 for the budget time period of December 2013 through November 2014. The Recipient

Organization is listed as Scripps, the Principal Investigator is Relator, the Administrative Official is Kay I. Wynne and the Signing Official is Lawrence Douglass. In terms of the individuals who have worked on the research project, the Progress Report lists Relator as PI, 4 calendar months (34% effort); a co-investigator Patrick Griffin, 1 calendar month (9%); a co-investigator Andrew Butler, 1 calendar month (9%), a co-investigator Theodore Kamenecka, 1 calendar month (9%), a staff scientist, 1 calendar month (9%), and a postdoctoral candidate, 9 calendar months (75%). Further, Scripps certifies in the Progress Report that the level of effort in the next budget period will not be reduced more than 25% or below the minimum amount of effort required by the NOA. Dr. Burris was not aware of any instance where Scripps reported that the level of effort would be reduced more than 25% or below the minimum amount of effort required by the NOA. Relator believes that if Scripps had reduced the committed level of effort by more than 25%, it would risk losing the grant funding.

86. NIH issued Notices of Award (“NOAs”) for each year of the four years of the grant project which funded the award. For example, the Notice of Award dated November 3, 2011 provided \$680,084 in federal funding for the budget period from December 2011 through the end of November 2012. The NOA dated April 19, 2012 increased the funding for that budget period by an additional \$64,299. The NOA dated November 23, 2012 provided \$669,947 in federal funding for the budget period from December 2012 through the end of November 2013. Each of these NOAs state that the recipient organization accepts the award and agrees to abide by the terms and conditions of the award when the recipient draws down funds from the grant payment system. Further, the award of federal grant money is based on the information included in the new grant application and is subject to the terms and conditions set for in the NOA, including compliance with federal regulations regarding effort reporting requirements.

c. **NIH Grant R01MH093429 “REV-ERB ligands for treatment of anxiety disorders”**

87. NIH awarded Scripps this \$4.6 million dollar research grant for a five-year project period which was subsequently extended to six years. This grant provided funding to research the potential utility of synthetic compounds that target the REV-ERB receptor for the treatment of anxiety disorders. This research is focused on developing new drugs that target a receptor known as REV-ERB for treatment of anxiety, and other behavioral disorders with fewer side effects than current drugs. The grant application listed Kaye I. Wynne, Vice President of the Office of Sponsored Programs at Scripps as the Authorized Representative and Lawrence Douglass signed the application. Key Personnel devoted the following time and effort to this grant: Relator as PI, 4 calendar months (34% effort); Theodore Kamenecka as Co-investigator, 1.2 calendar months (10% effort); Andrew Butler, as Co-investigator, 1.2 calendar months (10% effort); Michael Cameron as Co-investigator, .6 calendar months (5% effort); and Paul Kenny as Co-investigator, .3 calendar months (3% effort).

88. NIH issued Notices of Award (“NOAs”) funding the award for the budget periods. For example, the Notice of Award dated August 2, 2013 provided \$834,463 in federal funding for the budget period from August 2013 through the end of July 2014. The NOAs state that the recipient organization accepts the award and agrees to abide by the terms and conditions of the award when the recipient draws down funds from the grant payment system. Further, the award of federal grant money is based on the information included in the new grant application and is subject to the terms and conditions set for in the NOA, including compliance with federal regulations regarding effort reporting requirements.

d. **NIH Grant R01AA021298 “Treatment of Alcohol Induced Hepatic Injury with REV-ERB Ligands”**

89. NIH awarded this grant for \$544,500 for a two-year period of roughly from 2012 through 2014 which was subsequently extended to 2015. The grant provides funding to examine the potential utility of synthetic REV-ERB ligands for treatment of fatty liver associated with alcohol abuse. The grant application listed Kaye I. Wynne, Vice President of the Office of Sponsored Programs at Scripps as the Authorized Representative and Lawrence Douglass signed the application. Key Personnel devoted the following time and effort to this grant: Relator as PI, 1.2 calendar months (10% effort); a Postdoctoral Fellow, 5 calendar months (42% effort); a Staff Scientist 3 months (25% effort); and a Research Associate, 3 months (25% effort).

90. Before this grant application was approved, Scripps submitted a Just in Time Report to NIH on December 7, 2011 setting forth Relator's Other Support, meaning his current active sponsored research commitments as well as his pending grants. For current active projects, the Report lists Relator working 5.04 calendar months on grant R01 MH092769; 3.84 months on grant R01 DK080201; .60 months on grant R21 NS073047; and pending support as committing 4 calendar months to R01 MH09329 and potentially 4 other pending grant applications/resubmissions.

91. NIH issued Notices of Award ("NOAs") for each year of the grant project to fund the award. For example, the Notice of Award dated November 12, 2012 provided \$284,625 in federal funding for the budget period from December 2012 through the end of November 2013. All of the NOAs state that the recipient organization accepts the award and agrees to abide by the terms and conditions of the award when the recipient draws down funds from the grant payment system. Further, the award of federal grant money is based on the information included in the new grant application and is subject to the terms and conditions set for in the NOA, including compliance with federal regulations regarding effort reporting requirements.

2. Relator's New Grant Application Activity in 2012

92. Relator worked on the above approved grants throughout 2012 for which Scripps charged NIH 100% of Relator's salary and benefits, such as healthcare, life insurance and retirement. Relator, however, also worked on many new grants or resubmissions during that same time, each and cumulatively requiring substantial portions of Relator's time. Each of these projects named below was authorized by Scripps. Scripps improperly charged this new grant application and other research activity to the awarded grants, but such new application and other research work did not benefit the awarded grants. Specifically, during 2012 he worked on the following grant applications and research:

- a. **NIH Grant R01 DK098555 "Development of Novel Therapeutics for Treatment of NAFLD and NASH"**: Throughout 2012, Relator worked on the initial grant application which was submitted in June 2012 and then he continued to work throughout 2012 on the resubmission which was sent to NIH in February 2013. The initial application spanned over 60 pages and requested over \$4.2 million dollars in research funding. For the original submission Relator and the staff, among other things, conducted scientific literature research, designed experiments, monitored results, met with research staff, analyzed the data, prepared the results, drafted the proposal, finalized the application. The application included a detailed, specific research plan with scientific data describing the design of LXR inverse agonists for the treatment of liver disease. The resubmission required designing and monitoring additional experiments to address the comments of the reviewers, compiling and analyzing the results, etc., but the writing was less labor intensive since there was an initial application from which to work.

Relator estimates he expended 10% effort over the course of the year in preparing the initial application. Relator estimates his time and effort on the resubmission to be about 5% over the course of the year.

- b. **NIH Grant R01 GM106250 "Development of ERRg in vivo Chemical Probes"**: The initial application spanning 55 pages and requesting over \$2.3 million dollars in funding was submitted in June 2012 and resubmitted in March 2013. The work compiling the new application and resubmission are similar to the work described for the above grant. The focus of this research grant is to study developing drugs that target the ERRg receptor. Relator estimates he expended during 2012 8% effort on the initial application and 2% on the resubmission.

- c. **Cancer Project**: Relator worked on another project that required considerable effort during 2012. While no grant application was submitted while Relator was at Scripps, his work yielded a patent application filed by Scripps. It required at least 10% effort and was focused on the cancer project. Relator has publications that also illustrate the work that was performed outside the 100% funding.
- d. **Defense Advanced Research Projects Agency (DARPA) Grant “Development of Novel Drugs to Increase Wakefulness and Performance in Military Operational Personnel”**: Although submitted in February 2013, Relator worked on this preparing this grant in 2012. This grant sought \$7.2 million dollars to research drugs to keep military personnel awake and enhance performance. Although the application was 65 pages long, Relator estimates his effort at 5% because they were able to use some of the data generated for another project.
- e. **NIH Grant R21AA021298 “Treatment of Alcohol Induced Hepatic Injury with REV-ERB Ligands”**: This grant, discussed more fully above in paragraphs 88-90, was initially submitted in June 2011, resubmitted in March 2012 and subsequently awarded by the NIH. Relator estimates 3% effort in 2012 for the resubmission.
- f. **American Diabetes Association Grant**: This grant application, submitted in January 2012, was to cover the salary of a Postdoctoral Fellow for three years. It specified a particular Fellow in the grant and explained the proposed project. Relator estimates that he only expended 1% effort on this grant as they were able to use data they already had to explain the future research project.

93. Below is a chart setting forth the percentage of Relator’s time during 2012 expended in developing new grant applications, resubmissions and research as described in paragraphs 91(a) – (f) above.

(a)	10%	Initial Application
	5%	Resubmission
(b)	8%	Initial Application
	2%	Resubmission
(c)	10%	Cancer research
(d)	5%	Initial Application
(e)	3%	Resubmission
(f)	1%	Initial Application
Total	44%	

94. In sum, Relator’s time and effort spent compiling the above grant applications and resubmissions and research were improperly charged by Scripps to the awarded grants

detailed above. The chart above summarizes the percentage of time Relator spent on grant applications, submissions and research, all of which was authorized by Scripps during 2012 where 100% of his salary was charged by Scripps to awarded grants. This just represents an example as to one year (2012), for one individual and represents almost 44% of his time in 2012.

95. The grant applications, Just in Time Reports and other related reports, certifications, and requests for payment made by Scripps to the government on all of the awarded grants which Relator worked on during his tenure at Scripps, and specifically those submitted in connection with grants R01 DK080201, R01MH092769, R01MH093429, and R01AA021298 set forth in paragraphs 81-91 *infra* were false claims because they misrepresented the work effort of Relator and the researchers working under him because they included time and effort working on new grant applications and other work unrelated to the awarded grants. As discussed below, Relator contends based on his knowledge of the soft money policy and discussions with other PIs, that Scripps also falsely billed 100% of other researchers' time to awarded grants when those researchers worked on other non-awarded grant applications in the same year that 100% salary was billed to awarded grants.

3. Scripps Falsely Billed Awarded Grants for Researchers' Work on New Grant Application Activity

96. Throughout the relevant time period, Relator believes that Scripps systematically overbilled the salaries and benefits of many PIs, faculty and other researchers to awarded grants for their work on new grant application activity.

97. From 2008 through 2014, Scripps obtained over \$1.5 billion dollars in federal grant funding for over 2,800 research grants. Upon information and belief, Scripps overcharged these federal grants, as it did for the grants on which Relator was the PI, for the researchers'

salaries for time spent on work unrelated to the grants, *i.e.*, competitive grant writing and teaching.

98. Based on his personal knowledge and research, it is Relator's belief that all or most of the below faculty members covered 100% of their salary and other benefits through federal grant funding. The individuals listed below are faculty at Scripps who are working on several awarded grants during a year, and are most likely funding all or substantially all of their salaries through grants. Further, many of these faulty have teaching and other responsibilities, such as course directors, in the Ph.D. program. Those listed below with an asterisk "*" have teaching responsibilities at Scripps, including serving as course directors. Therefore, upon information and belief, Scripps is overcharging award grants for costs associated with writing new grant applications/resubmissions and teaching in the Ph.D. program, costs which are not properly allocable to already-awarded grants. As alleged in Section V.D. below, the faculty, including PIs, were unaware of this fraud as Scripps had failed to implement adequate policies, procedures, and training to educate its faculty and other researchers as to compliance with the time and effort reporting requirements.

Phil Baran, Ph.D.*	Professor	Scripps La Jolla
Dale Boger, Ph.D.*	Professor/Chair	Scripps La Jolla
Dennis Burton, Ph.D.*	Professor	Scripps La Jolla
Bridget Carragher, Ph.D.	Professor	Scripps La Jolla
Hollis Cline, Ph.D.*	Professor	Scripps La Jolla
Benjamin Cravatt, Ph.D.	Professor/Chair	Scripps La Jolla
Cindy Ehlers, Ph.D.	Professor	Scripps La Jolla
John Elder, Ph.D.	Professor	Scripps La Jolla
Michael Farzan, Ph.D.	Professor	Scripps Florida
Ann Feeny, Ph.D.*	Professor	Scripps La Jolla
Philippe Gallay, Ph.D.	Professor	Scripps La Jolla
Oliver George, Ph.D.	Asst. Professor	Scripps La Jolla
Joel Gottesfeld, Ph.D.	Professor	Scripps La Jolla
Kim Janda, Ph.D.	Professor	Scripps La Jolla

Jeffery Kelly, Ph.D.*	Professor/Chair	Scripps La Jolla
Joseph Kissil, Ph.D.*	Asst. Professor	Scripps Florida
Kirill Martemyanov, Ph.D.	Assoc. Professor	Scripps Florida
Barbara Mason, Ph.D.	Professor	Scripps La Jolla
Michael Mcheyzer-Williams*	Professor	Scripps La Jolla
Ulrich Mueller, Ph.D.*	Professor/Chair	Scripps La Jolla
Michael Oldstone, Ph.D.*	Professor	Scripps La Jolla
Loren Parsons, Ph.D.	Professor	Scripps La Jolla
Ardem Patapoutian, Ph.D.	Professor	Scripps La Jolla
James Paulson, Ph.D.	Professor	Scripps La Jolla
Marisa Roberto, Ph.D.	Assoc. Professor	Scripps La Jolla
Hugh Rosen, M.D., Ph.D.*	Professor	Scripps La Jolla
Gaven Rumbaugh, Ph.D.*	Assoc. Professor	Scripps Florida
Paul Russell, Ph.D.	Professor	Scripps La Jolla
Pietro Sanna, Ph.D.*	Assoc. Professor	Scripps La Jolla
Erica Sapphire, Ph.D.*	Professor	Scripps La Jolla
Peter Schultz, Ph.D.*	Professor	Scripps La Jolla
Andrew Su, Ph.D.	Assoc. Professor	Scripps La Jolla
Peiqing Sun, Ph.D.*	Assoc. Professor	Scripps La Jolla
Luc Teyton, Ph.D.*	Professor	Scripps La Jolla
Eric Topol, M.D.*	Professor	Scripps La Jolla
Susana Valente, Ph.D.*	Assoc. Professor	Scripps Florida
Friedbert Weiss, Ph.D.	Professor	Scripps La Jolla
J. Lindsay Whitton, Ph.D.	Professor	Scripps La Jolla
James Williamson, Ph.D.*	Dean/Professor	Scripps La Jolla
Ian Wilson, Ph.D.*	Professor/Chair	Scripps La Jolla
Peter Wright, Ph.D.*	Professor	Scripps La Jolla
John Yates, Ph.D.	Professor	Scripps La Jolla
Michael Zwick, Ph.D.*	Assoc. Professor	Scripps La Jolla

99. Documents proving the specific false claims with respect to other federally funded grants are within the possession and control of Defendant. Relevant documents demonstrating the fraud include: grant applications and resubmissions (both awarded and not awarded), Notice of Grant Awards, Just in Time Reports, Progress Reports, other reports showing the level of time and effort committed by the researchers, internal Scripps effort reports,

internal Scripps documented payrolls, and Scripps' policies, procedures, training materials regarding effort reporting.

D. Scripps Failed to Implement Adequate Policies, Procedures, Training and Internal Controls for Tracking and Accurately Billing Awarded Grants for Researchers' Time and Effort

100. Throughout the relevant time period, Scripps has recklessly or intentionally failed to implement the policies, procedures and internal controls necessary to prevent improperly charging awarded grants for unallowable costs, such as costs associated with new grant application activity. To the best of his recollection, Relator has never received any policies, procedures or training about how to accurately account for the significant amount of time and effort spent drafting and generating the scientific data for new grant applications and resubmissions. It is Relator's belief that the other PIs at Scripps were similarly uninformed. This lack of training, combined with Scripps' recklessly inadequate internal controls for tracking new grant application activity, its soft money policy that researchers charge 100% of their salaries to awarded grants, and Scripps limited funding sources outside of federal grants, has led Scripps to knowingly overcharge federal research grants.

101. As discussed above, in order to charge an award for an employee's salary or portion thereof, Scripps must maintain "documented payrolls" and effort reports reflecting the **after-the-fact actual activity of each employee and an accurate distribution of the activities of the employee**. The effort reports must be signed by the individual employee and prepared at least monthly by the institution. These effort reporting requirements must be established and administered at the institutional level.

102. Although Scripps did distribute monthly accounting payrolls and effort reports to researchers, these reports did not comply with federal regulations as they did not accurately or reasonably reflect the actual time and effort devoted to awarded grants and were misleadingly

ambiguous. Neither report specifically accounts for time spent on grant proposal activity. Relator was never asked to state the amount of time spent on new grant applications or to separate out the time spent on awarded grants from that spent on grant applications. In addition, they were wholly inadequate because Scripps failed to provide any training or guidance to researchers as to how to verify the accuracy of the distribution of effort contained therein. No one at Scripps ever instructed Relator or to his knowledge, other faculty, to separate out grant application time or to not count such time in effort reporting.

1. Internal Payroll Reports

103. The internal, monthly accounting payroll print-out showed, among many other things, the PI's research grants, the personnel working on the grants and the distribution of their effort on the grants expressed as percentages. The document also included many pages of detailed expenses charged to each grant. Although the document had a line for the PI's signature, Relator never signed the payroll documents. Scripps never explained the significance of the document and never followed up with Relator asking for him to sign it.

2. Internal Effort Reports

104. Although, Scripps sent a two-page effort report to Relator asking for him to sign each page every month, it never explained how to fill it out, its significance, or why he needed to sign it. Relator was never clear as to whether it was a financial, accounting or compliance document. The first page of the effort report typically contained the following:

For the period [one month period listed], my effort should be as follows:

	Percent
Research & Training	_____
Administration	_____

100% Total

Signed: _____

Administration is defined as functions which pertain to common or joint objectives and cannot be readily identified with a specific research grant or contract.

The second page of the effort report listed the employee ID number, various Account Numbers and Hours associated with those Account Numbers and Total Hours of 160. The 160 hours was always already printed on the form.

105. On a monthly basis, Scripps asked employees to sign the first and second pages and return to the Office of Sponsored Programs. However, Scripps never explained or trained employees on the meaning of “Research & Training” or “Administration” beyond the very general definition of “Administration” listed on the first page of the report. Specifically relevant to this complaint, Scripps never provided guidance about how to classify the employee’s effort spent writing new grant applications. It was unclear whether it would be considered “research” or “administration.” This is a significant failure for a “soft money” institution such as Scripps which expects its researchers to fund their salaries with grant funding, yet does not train them as to compliance. Further, Scripps never explained how the hours associated with the account numbers were calculated. Also, because the account numbers are internal Scripps numbers without any description, it was not readily apparent what specific grants or accounts are associated with the hours worked. In sum, the effort report form which was required to be signed by PIs was knowingly misleading and ambiguous in that it did not distinguish between time and effort spent on awarded grants as opposed to new grant applications, teaching, or other activities.

3. Relator’s Experience at Saint Louis University

106. In contrast to his experience at Scripps, at Relator's current position at Saint Louis University (SLU) in St. Louis, Missouri, SLU has required effort-reporting training for all faculty, researchers and staff. During his more than 5 years at Scripps, Relator, and to his knowledge, other faculty, never had such training. SLU maintains a robust compliance office that monitors effort reporting and actually conducts audits. Effort reports for all investigators are also filed online and must be signed by investigators. Non-compliance with filing effort reports is not allowed. Effort is also monitored very closely and when PIs submit new applications, it has been made very clear that 100% effort on NIH funds is **not possible** based on the fact that a PI cannot realistically spend all his or her effort on sponsored projects since there are other tasks that are not project related. At SLU, if a researcher approaches or even proposes billing coming close to 100% of time and effort to sponsored projects, it triggers a compliance person to investigate.

107. None of the above compliance activities took place on any systematic basis during his more than 5 years at Scripps. Nor were researchers ever informed, to Relator's knowledge while he was employed at Scripps, that time spent on grant applications could not be allocated to awarded grants. It was not until Relator was employed at SLU that he learned through the compliance personnel at SLU that billing awarded grants for time spent on grant applications was unlawful. He thought Scripps was complying with the law while he was employed by Scripps.

108. As a recipient of over \$1.5 billion dollars in federal grant funding during the relevant time period, Scripps has the responsibility to be a good steward of these funds. By recklessly or intentionally failing to institute the necessary policies and practices, Scripps has defrauded the United States by submitting false claims to obtain awarded grant money, knowing

that researchers spend considerable time and effort on new grant application activity not chargeable to awarded grants. Further, the public has been affected as well in that time spent on new grant application activity detracts from the effort committed to the medical research for which the grant was funded. In addition, Scripps is given an unfair advantage over institutions that have to compensate their researchers for time spent drafting new applications/submissions.

VI. COUNTS

Count I Federal False Claims Act 31 U.S.C. §§3729(a)(1)(A), and (a)(1)(B)

109. Relator alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

110. As discussed above, Scripps made misrepresentations in grant applications and other reports about the level of effort devoted by the key research personnel. Further, Scripps expressly and/or impliedly certified compliance with federal law governing grants. These representations were false because Scripps knowingly failed to comply with federal law and accurately reflect the level of effort committed by the key personnel on the awarded grants in that it failed to take into account the considerable time and effort expended on new grant application activity which is not chargeable to awarded grants.

111. As a result, Defendant submitted false claims or caused false claims to be submitted when it submitted grant applications and other reports containing personnel effort commitments and when it made claims for payment from the grants, all in violation of federal effort reporting law and regulations.

112. Through the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval in violation of Section 3729(a)(1)(A).

113. Through the acts described above, Defendant knowingly made, used, or caused to be made or used false or fraudulent records and statements, material to a false or fraudulent claim to the United States for payment or approval in violation of Section 3729(a)(1)(B).

114. The United States Government and its officers, employees and agents, unaware of the falsity of the records, statements, and claims made or caused to be made by the Defendant paid and continues to pay claims that would not be paid but for the Defendant's illegal and fraudulent practices.

115. By reason of the acts of Defendant, the United States has been damaged, and continues to be damaged, and therefore is entitled to treble damages under the False Claims Act in an amount to be determined at trial, plus a civil per claim penalty in the maximum amount permitted by law for each violation.

Count II
Federal False Claims Act 31
U.S.C. §§3729(a)(1)(G)

116. Relator alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

117. As discussed above, Scripps made representations in grant applications and other reports about the level of effort committed by the key research personnel. Further, Scripps expressly and impliedly certified compliance with federal law governing grants. These representations were false because Scripps knowingly failed to comply with federal law and accurately reflect the level of effort committed by the key personnel on the awarded grants in that it failed to take into account the considerable time and effort expended on new grant application activity which is not directly chargeable to awarded grants. Further, Defendant failed to implement adequate policies, procedures, training and internal controls to accurately track and

bill awarded grants and reconcile any discrepancies between promised and actual effort. Thus, Defendant's failure to properly reconcile the effort commitment with the actual effort expended, served to conceal or avoid an obligation to pay or refund money to the government.

118. Through the acts described above, Defendant knowingly made, used or caused to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

119. The United States Government and its officers, employees and agents, unaware of the falsity of the records, statements, and claims made or caused to be made by the Defendant, paid and continues to pay claims that would not be paid but for the Defendant's illegal and fraudulent practices.

120. By reason of the acts of Defendant, the United States has been damaged, and continues to be damaged, and therefore is entitled to multiple treble damages under the False Claims Act in an amount to be determined at trial, plus a civil per claim penalty in the maximum amount permitted by law for each violation.

PRAYER

WHEREFORE, Relator prays for judgment against the Defendant as follows:

121. That Defendant cease and desist from violating *31 U.S.C. §3729, et seq.*;

122. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of *31 U.S.C. §3729, et seq.*;

123. That Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

124. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

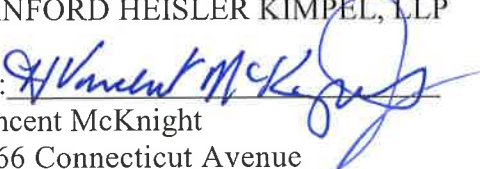
125. That Relator recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: May 19, 2015

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CERTIFICATE OF SERVICE

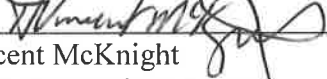
I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been furnished by Certified Mail, Return Receipt Requested, this 19th day of May, 2015 to the following:

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